

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CHR. HANSEN HMO GMBH,

Plaintiff and
Counterclaim Defendant,

v.

GLYCOSYN LLC,

Defendant and
Counterclaim Plaintiff,

v.

ABBOTT LABORATORIES,

Counterclaim Defendant.

No. 22-cv-11090-NMG

MEMORANDUM AND ORDER ON GLOCOSYN LLC'S MOTION TO COMPEL

CABELL, U.S.M.J.

I. Introduction

In this complex action, counterclaim plaintiff Glycosyn LLC ("Glycosyn") accuses counterclaim defendants Chr. Hansen HMO GMBH ("Chr. Hansen") and Abbott Laboratories ("Abbott") of infringing its patents, which cover a process for manufacturing certain complex sugars. Through this motion, (D. 134), Glycosyn seeks an order compelling Chr. Hansen to produce several categories of documents relating to three different bacteria strains Chr. Hansen uses or has used to produce these complex sugars. Chr. Hansen

opposes the motion.¹ (D. 140). For the following reasons, the motion to compel is granted in part and denied in part.

II. Relevant Background

Glycosyn holds two patents that cover methods of producing complex sugars known as human milk oligosaccharides, so called because they occur naturally in human milk. These oligosaccharides promote immune health in infants. The patents, U.S. Patent Nos. 9,453,230 ("the '230 Patent") and 9,970,018 ("the '018 Patent"), are specifically directed toward production of fucosylated oligosaccharides, which are oligosaccharides comprised of simple sugars glucose, galactose, and fucose. Two types of fucosylated oligosaccharides are relevant here: 2'-FL and 3-FL.²

Historically, artificial production of fucosylated oligosaccharides has proved to be difficult and costly. However, Glycosyn engineered a process to genetically modify strains of *E. coli* bacteria such that they would produce either 2'-FL or 3-FL in commercially viable quantities, depending on the specific genetic

¹ Abbott also filed an opposition to the motion to compel while expressing uncertainty as to whether the motion was directed to Abbott in the first place. (D. 138). As discussed below, to the extent that Glycosyn also seeks to compel Abbott to produce the documents at issue, the motion is denied.

² Fucosylated oligosaccharides are categorized based on (1) whether the fucose molecule is bonded with the galactose molecule or the glucose molecule and (2) where the bond occurs. For example, 2'-FL is so named because the fucose molecule bonds with the second carbon atom of the galactose molecule. Compare that to 3-FL, where the fucose molecule bonds with the third carbon atom of the glucose molecule.

modification. That process is the subject of the '018 Patent and the '230 Patent.³

Glycosyn and Chr. Hansen both produce fucosylated oligosaccharides on a commercial scale. Chr. Hansen supplies fucosylated oligosaccharides to Abbott. Abbott, in turn, uses these oligosaccharides in some of its baby formula products.

In 2018, Glycosyn filed a complaint with the International Trade Commission ("ITC") against Jennewein Biotechnologie GMBH ("Jennewein"), Chr. Hansen's predecessor in interest. *Certain Human Milk Oligosaccharides and Methods of Producing the Same*, Inv. No. 337-TA-1120, 2020 WL 3073788, at *1 (USITC June 8, 2020), *aff'd sub nom. Jennewein Biotechnologie GmbH v. Int'l Trade Comm'n*, No. 2020-2220, 2021 WL 4250784 (Fed. Cir. Sept. 17, 2021). Initially, the complaint asserted that Jennewein infringed both the '230 Patent and the '018 Patent, but Glycosyn later withdrew the allegations related to the '230 Patent. *Id.* Ultimately, the ITC considered whether three different strains of *E. coli* bacteria developed by Jennewein -- #1540, #2410, and TTFL12 -- infringed the '018 Patent. *Jennewein Biotechnologie*, 2021 WL 4250784, at *2

³ The idea of using *E. coli* to produce 2'-FL is not original to Glycosyn. Glycosyn's innovation, as captured in the patents, consists of a sequence of two gene edits that result in a lower level of an enzyme called β -galactosidase. β -galactosidase cleaves lactose into separate glucose and galactose molecules, which leaves less lactose available to bond with fucose to make 2'-FL and 3-FL. At the same time, having some β -galactosidase activity is helpful to break down excess lactose before harvesting the 2'-FL or 3-FL. Glycosyn's process is intended to reach a happy medium.

(summarizing ITC proceedings). The ITC determined that #1540 and #2410 infringed the '018 Patent but TTFL12 did not. *Id.*

In the wake of the ITC's decision (and the Federal Circuit's affirmance), Jennewein, and later Chr. Hansen, purportedly stopped using the #1540 strain to produce 2'-FL for sale in American markets.⁴ Instead, Chr. Hansen switched to a strain known as #1242, which was not considered in the ITC action. Chr. Hansen contends that it continues to use #1242 to produce 2'-FL for products sold in the United States, including Abbott's baby formulas. Similarly, Chr. Hansen uses a strain known as JBT-3FL to produce 3-FL for use in products sold in the United States.

Chr. Hansen filed the current action against Glycosyn seeking a declaratory judgment of invalidity and non-infringement of the '018 Patent. (D. 1). Glycosyn filed a counterclaim against Chr. Hansen and a third-party complaint against Abbott, accusing both of infringing the '018 Patent. (D. 15). The court recently granted Glycosyn leave to file an amended counterclaim to add allegations that Chr. Hansen and Abbott infringed the '230 Patent. (D. 185). Chr. Hansen has filed a motion to strike portions of Glycosyn's infringement contentions as to any strains other than the #1540 strain. (D. 119). Glycosyn has filed a motion for leave

⁴ It is not clear from the record whether Jennewein or Chr. Hansen ever used the #2410 strain to produce fucosylated oligosaccharides destined for the United States or elsewhere.

to serve amended infringement contentions regarding the '230 Patent. (D. 177). Those motions are currently pending.

III. Legal Standard

A party moving to compel discovery bears the initial burden of showing the relevance of the information sought. *DMO Norwood LLC v. Kia Am., Inc.*, --- F. Supp. 3d ---, 2023 WL 5353744, at *2 (D. Mass. 2023). Once the movant makes this showing, the burden shifts to the nonmoving party to show that the requested discovery is nonetheless improper. *Id.*

For requested materials to be discoverable, they must be both "relevant to any party's claim or defense and proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1). The proportionality analysis considers "the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." *Id.* While the information sought must be relevant to a party's claim or defense, it need not be narrowly tailored to prove a claim or defense, as materials may be discoverable even if they are not admissible in evidence. *Id.*; see *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978) ("[D]iscovery is not limited to issues raised by the pleadings, for discovery itself is designed to help define and clarify the issues.").

Because this action centers on “the infringement, validity, or enforceability of a United States Patent,” it is also governed by Local Rule 16.6. L.R. 16.6(a). Local Rule 16.6(d) sets out each party’s obligation to make certain automatic disclosures in addition to those required by Federal Rule of Civil Procedure 26(a)(1). For the patentee, these automatic disclosures include, inter alia, infringement claim charts that identify “each accused product and/or method” and provide “an element-by-element description of where and how each element of each asserted claim is found in each accused product or method.” L.R. 16.6(d)(1)(A). An accused infringer must disclose several categories of information, including technical documents, product samples, source code (where applicable), noninfringement claim charts, invalidity claim charts, other grounds for invalidity, supporting evidence for any asserted invalidity defense, and the identity of all real parties in interest. L.R. 16.6(d)(4). The rule further provides that “[t]he parties’ failure to agree on the sufficiency of the patentee’s disclosures . . . shall not entitle the accused infringer to avoid or delay its disclosure obligations in subsection (d)(4).” L.R. 16.6(d)(3).

IV. Discussion

Glycosyn seeks five categories of information from Chr. Hansen: batch records, production protocols, gene maps, test records, and laboratory notebooks. Glycosyn seeks this

information as to #1242, #1540, TTFL12, and JBT-3FL, although it indicated at the hearing on this motion that it would accept a more limited production as to #1242 and TTFL12. Chr. Hansen asserts (and Glycosyn does not dispute) that it already produced these materials to Glycosyn as to the #1540 strain in the previous ITC action.⁵ Chr. Hansen further argues that it has provided sufficient materials to Glycosyn as to the other strains and that the further discovery Glycosyn seeks is not proportional to the needs of the case. The court largely agrees with Chr. Hansen.

A. *#1242 and TTFL12*

Glycosyn does not contend that the #1242 or TTFL12 strains infringe the '018 Patent or the '230 Patent. (D. 120-18, email from Glycosyn's counsel to Chr. Hansen's counsel). Glycosyn's concern is that Chr. Hansen has covertly continued to use the #1540 strain to produce 2'-FL for American markets while falsely representing that it was using the #1242 strain. Glycosyn bases its suspicions in part on the fact that Chr. Hansen (or Jennewein) apparently developed the #1242 strain before the #1540 strain⁶ and in part on Chr. Hansen's reluctance to provide full strain and batch records, which Glycosyn interprets as concealment.

⁵ The parties have agreed that discovery from the ITC action may be used in this case.

⁶ The implication here is that the #1242 strain must be inferior to the #1540 strain. Otherwise, the argument goes, Jennewein would not have used the #1540 strain to produce 2'-FL prior to the ITC action if it already had the #1242 strain.

Chr. Hansen argues that Glycosyn's suspicions are unfounded. In support of that argument, Chr. Hansen points to the Customs and Border Patrol ("CBP") certifications dating back to June 2020 that it has produced in this action. In those certifications, Chr. Hansen affirmed, under penalty of perjury, that each batch of 2'-FL it imported into the United States was made using the #1242 strand. Glycosyn, for its part, does not contest that Chr. Hansen has produced those certifications. Instead, Glycosyn argues that it needs Chr. Hansen's batch records to test the certifications' veracity, especially since CBP does not independently verify the information Chr. Hansen provides.⁷

Glycosyn's concerns about whether and when Chr. Hansen imported allegedly infringing strains into the United States makes the batch records relevant to the subject matter of this case. While the veracity of Chr. Hansen's certifications to CBP is somewhat tangential to Glycosyn's core infringement claims, that does not make the issue totally irrelevant. *See Oppenheimer Fund*, 437 U.S. at 351 ("discovery is not limited to issues raised by the pleadings"); *see also Hudson-RPM Distributions, LLC v. Bowditch & Dewey, LLP*, Civil Action No. 19-cv-40095-TSH, 2021 WL 9649662, at

⁷ Glycosyn also argues that the requested discovery is relevant to damages. Specifically, Glycosyn needs to know when Chr. Hansen and Abbott were using infringing strains and noninfringing strains to calculate its damages. This is, in essence, a repackaged version of Glycosyn's argument that the CBP certifications are insufficient to show when and whether Chr. Hansen used the #1242 strain instead of the #1540 strain.

*3 (D. Mass. Feb. 12, 2021) (“the standard for relevance in discovery is low”).

Of course, relevance alone does not render materials discoverable. Chr. Hansen argues that the discovery requests at issue are unduly burdensome and thus not “proportional to the needs of the case.” Fed. R. Civ. P. 26(b)(1). Chr. Hansen asserts, with some support, that producing records for every batch of 2’-FL it has produced would require hundreds of hours of manual document collection. This would be a substantial burden. See *In re Betapharm Arzneimittel GmbH*, No. 23-mc-91600-IT, 2024 WL 421996, at *4-*5 (D. Mass. Feb. 5, 2024) (finding request burdensome where it “would take hundreds of hours of effort to categorize, redact, and prepare for use” requested records); see also *Fine v. Sovereign Bank*, Civil Action No. 06-cv-11450-NG, 2008 WL 11388664, at *4 (D. Mass. July 2, 2008) (affirming magistrate judge’s determination that discovery requiring “hundreds of employee hours” of review and substantial expense was unduly burdensome).

Glycosyn argues that Chr. Hansen could easily produce the requested batch records, notwithstanding its present objections, based on Jennewein’s previous representation that it could “identify the strain used to produce each lot number of 2’-FL within four hours of a request.” *Certain Human Milk Oligosaccharides and Methods of Producing the Same*, Inv. No. 337-

TA-1120, 2019 WL 5677974, at *24 (USITC Sept. 9, 2019), *aff'd in part and rev'd in part*, 2020 WL 3073788. This argument is facially attractive, but it elides two potentially important points. First, there is likely a meaningful difference between simply identifying the strain used to produce a particular batch of 2'-FL and collecting a full set of records for that batch. Second, even if Chr. Hansen could pull together all the relevant documents for one batch within four hours, that is entirely consistent with the idea that it would require hundreds of hours to collect documents for the scores of batches Chr. Hansen has produced. As such, Chr. Hansen's ability to identify one batch's strain within four hours does not necessarily mean that producing all batch records would not be significantly burdensome.

Again, it bears restating that Glycosyn does not allege that the #1242 or TTFL12 strains infringe its patents, which makes the relevance of records about those strains unclear at best. Nonetheless, Glycosyn argues that it needs batch records to test Chr. Hansen's sworn certifications to CBP that it uses the #1242 strain, and not the #1540 strain, to make the 2'-FL it imports into the United States. In this context, the batch records are relevant to this action, but only tangentially so, especially since there is no basis on the record to suspect that Chr. Hansen has routinely committed perjury by deceiving CBP. Weighed against this marginal relevance is the significant burden collecting and

producing the batch records would impose on Chr. Hansen. Balancing these considerations, the court finds that Glycosyn's discovery requests are not proportional to the needs of the case. See *Doe v. Sanderson*, Civil Action No. 16-cv-12068-IT, 2021 WL 828379, at *2 (D. Mass. Mar. 4, 2021) (finding burden or expense of proposed discovery outweighed likely benefit based on "marginal relevance" of discovery sought). Accordingly, the motion to compel is denied as to the #1242 and TTFL12 strains.

B. *JBT-3FL*

Unlike the two strains discussed above, Glycosyn alleges that the JBT-3FL strain infringes the '018 Patent. The parties' dispute about Glycosyn's requests related to this strain turn in part on their arguments about the adequacy of Glycosyn's infringement contentions. Chr. Hansen asserts that "Glycosyn has failed to provide an element-by-element description of where and how each element of each asserted claim is found in each accused product or method for JBT-3FL, as required by the Local Rules." (D. 140, p. 17). Chr. Hansen asks this court to reserve its ruling on the motion to compel until its motion to strike Glycosyn's infringement contentions (D. 119) is decided.

As mentioned above, Local Rule 16.6(d)(4) requires an accused infringer to produce certain documents automatically. Local Rule 16.6(d)(3) directs that the accused infringer must make this production notwithstanding the parties' disagreement about the

sufficiency of the patentee's disclosures. The text of the rule reveals no exception for cases where the patentee's disclosures (allegedly) fall well short of the requirements imposed by Local Rule 16.6(d)(1), nor is the court aware of any cases interpreting the rule this way. Therefore, Chr. Hansen must provide the full range of discovery contemplated by Local Rule 16.6(d)(4) notwithstanding its arguments about the insufficiency of Glycosyn's infringement contentions.⁸

To the extent that the discovery Glycosyn seeks goes beyond the requirements of Local Rule 16.6(d)(4), the court agrees with Chr. Hansen that it makes the most sense to defer ruling on those requests until Chr. Hansen's motion to strike is resolved. As such, the court will deny the motion to compel without prejudice as to discovery regarding JBT-3FL other than what is covered by Local Rule 16.6(d)(4). Glycosyn may renew its motion following a ruling on Chr. Hansen's motion to strike to the extent that the motion remains viable based on that ruling.

C. Discovery From Abbott

At the hearing on this motion, Glycosyn clarified that the motion is directed to Abbott as well as Chr. Hansen because Abbott has a contractual right to obtain some or all of the requested documents from Chr. Hansen. "[T]he court must limit the frequency

⁸ Chr. Hansen asserts that it has already produced discovery sufficient to meet its obligations under Local Rule 16.6(d)(4). The court makes no finding as to whether Chr. Hansen has already complied with the rule.

or extent of discovery otherwise allowed by these rules or by local rule if it determines that[] the discovery sought . . . can be obtained from some other source that is more convenient, less burdensome, or less expensive.” Fed. R. Civ. P. 26(b)(2)(C). Here, Chr. Hansen is clearly a more convenient source than Abbott given that Chr. Hansen, and not Abbott, actually possesses the requested records. Therefore, the court denies the motion to compel as to Abbott.

V. Conclusion

For the reasons discussed above, Glycosyn’s motion to compel (D. 134) is GRANTED IN PART and DENIED IN PART. The motion is granted in that Chr. Hansen must make the disclosures required by Local Rule 16.6(d)(4) as to JBT-2FL. The motion is denied without prejudice to the extent it seeks other discovery from Chr. Hansen regarding JBT-3FL. The motion is otherwise denied.

So ordered.

/s/ Donald L. Cabell
DONALD L. CABELL, U.S.M.J.

DATED: May 10, 2024